

Manual Vital Signs Reliably Predict Need for Life-Saving Interventions in Trauma Patients

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Objective: Various types of diagnostic and monitoring techniques are available in the prehospital environment. It is unclear how increasing complexity of diagnostic equipment improves the ability to predict the need for a life-saving intervention (LSI). In this study, we determined whether the addition of diagnostic equipment improved the predictive power of vital signs and scores obtained only by physical examination.

Methods: Institutional review board approval was obtained for an analysis of 793 prehospital trauma patient records collected during helicopter transport by Emergency Medical Services personnel. Exclusion of severe head injuries and patients with incomplete data resulted in 381 patients available for analysis. Data sets were classified on the basis of the instrumentation requirements for capturing the given measurements and were defined by three groups: Group 1, vital signs obtained with no equipment (radial, femoral,

and carotid pulse character; capillary refill; motor and verbal components of the Glasgow Coma Scale [GCS]); Group 2, Group 1 plus eye component of the GCS and pulse oximetry (SpO₂); and Group 3, Group 2 plus fully automated noninvasive blood pressure measurements, heart rate, end-tidal carbon dioxide, and respiratory rate. LSIs performed during transport and in the hospital were recorded. Data were analyzed using a multivariate logistic regression model to determine which vital signs were the best predictors of LSI.

Results: Radial pulse character and GCS verbal and motor components had the best predictive power for the need of a prehospital LSI in Group 1 (receiver operating characteristic [ROC] curve, 0.97). Radial pulse character together with the eye component of the GCS and the motor component of the GCS provided the best prediction of a need for a prehospital LSI for Group 2 (ROC curve, 0.97). Addition of all

supplementary vital signs measured by an automated monitor (Group 3) resulted in an ROC curve of 0.97. Given an abnormal radial pulse character (weak or absent) and abnormal GCS verbal and motor components, the probability of needing an LSI was greater than 88%.

Conclusion: In this cohort of patients, predicting the need for an LSI could have been achieved from GCS motor and verbal components and radial pulse character without automated monitors. These data show that simple and rapidly acquired manual measurements could be used to effectively triage non-head-injured trauma casualties. Similar results were obtained from manual measurements compared with those recorded from automated medical instrumentation that may be unavailable or difficult to use in the field.

Key Words: Trauma, Prehospital, Triage, Hemorrhage, Glasgow Coma Scale (GCS), Life-saving intervention (LSI).

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Hemorrhage continues to be the leading preventable cause of death on the battlefield; thus, development of new approaches for triage, diagnosis, and treatment in austere environments has continued to be a priority for de-

creasing mortality in combat casualties. Similarly, uncontrolled hemorrhage is a leading cause of early trauma death in the civilian trauma population. Currently, uncontrolled hemorrhage accounts for approximately 80% of civilian and 50% of combat deaths.^{1,2} Several triage criteria have been advocated in the civilian setting to determine injury severity, mode of transport, and patient destination for the triage of trauma patients.^{3–16} Most trauma systems currently use criteria or scales based on the patient's initial physiologic condition along with combinations of mechanism of injury, anatomy and location of injury, and sometimes premorbid conditions to aid in the triage process. However, to monitor physiologic data for purported optimal treatment and triage of trauma patients, newer technology has allowed medical providers access to an ever-increasing complex array of physiologic parameters. These new electronic monitors provide large amounts of physiologic information to providers well beyond what may be readily obtained by physical examination. Pulse oximetry, electrocardiography (ECG), end-tidal carbon dioxide (EtCO₂), and intermittent mean arterial pressure are some examples of data acquired by these increasingly sophisticated instruments.

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Presently, data available to medics in the field are usually limited to using a single set (or at best two sets) of noninvasive vital sign measurements of the patient throughout the prehospital care phase, if measured at all.¹⁷ Consequently, treatment options and decisions have typically not been based on continuous trended data but instead have been based on the experience of the medic and the limited set of vital sign measurements taken at some point during the treatment and transport phase. As a result, emergency personnel have to make treatment and triage decisions on the basis of limited physiologic data without the benefit of observable vital sign trends and patient progression. Furthermore, operational limitations frequently prevent advanced monitoring equipment to be located at the site of initial treatment. This is perceived as potentially detrimental to optimal care. This lack of advanced diagnostic equipment necessitates the development of triage and treatment methods based on rapidly available resources that allow prehospital personnel to more reliably predict outcome of the patient and the possible need for performing of a life-saving intervention (LSI).¹⁸

As patients move through the treatment chain, better and more effective treatment options and equipment may be available with which to perform optimal triage, diagnosis, and treatment.^{18–22} However, it is unclear whether using increasingly complex diagnosis equipment early in the evaluation of trauma patients improves the ability of the prehospital providers to determining the need for an LSI or predict outcome. The hypothesis of this study was that the addition of automated systems during the treatment phase would increase the ability to predict the need for an LSI.

PATIENTS AND METHODS

This study was approved by the Institutional Review Board of the University of Texas Health Science Center, Houston, Texas, and the U.S. Army Human Subject Research Review Board, Ft. Detrick, Maryland. A random convenience sample of trauma patients transported from the scene by the Memorial Hermann Life Flight helicopter service to the Level I unit at the Memorial Hermann Hospital in Houston, Texas, was used for the study. This study examined the medical records of 920 patients recorded on the Trauma Vitals database between August 2001 and April 2004. When excluding head injuries (head Abbreviated Injury Scale score ≥ 3), a total of 783 patients were eligible for analysis. Where appropriate, quartiles were used for description of the measured physiologic data. Data for the pulse character were not initially recorded and resulted in elimination of 339 records created from August 2001 until May 2002. Analysis of the Spo_2 variable was further constrained by eliminating 63 patients that were dead at admission to the hospital or had Spo_2 values of 0% recorded. Also excluded were patients in which the electronic monitor was not able to record a Spo_2 value during the transport. This resulted in a final group of 381 patients for multivariate analysis.

Table 1 Cohort Demographics (Total LSIs)

Variable	Patients with LSI (n = 126)	Patients without LSI (n = 255)
Age (yr)	35 \pm 16	37 \pm 15
Sex		
Male (%)	75	71
Female (%)	25	29
MOI		
Blunt (%)	85	90
Penetrating (%)	15	10
ISS	15 \pm 10	10 \pm 8
GCS score		
Motor	2.5 \pm 2	5.9 \pm 0.3
Verbal	1.6 \pm 1.2	4.6 \pm 0.7
Eye	1.5 \pm 1.0	3.8 \pm 0.5
Total	5.6 \pm 3.8	14.3 \pm 3.2

MOI, mechanism of injury; ISS, Injury Severity Score.

The Life Flight helicopter service consists of three Eurocopter BK 117Bs distributed at three different geographic locations within the Houston metropolitan area. Aircraft personnel consist of a pilot, flight medic, and nurse with experience transporting a high volume of trauma patients. Flight reviews of critical patients are performed on a monthly basis to further train flight personnel. Data were collected for this study using both an automated data collection device for capturing values generated by the on-board vital signs monitor in addition to the standard run sheet filled out by emergency personnel for every patient and retrospective patient chart reviews.

Table 1 shows the demographics of the study cohort. Vital signs, Glasgow Coma Scale (GCS) score, capillary refill, age, gender, mechanism of injury, pulse character, and incident demographics were recorded manually in addition to any fluids and interventions performed during transport. Prehospital LSIs were defined on the basis of procedures outlined by the Life Flight service emergency protocols. Hospital-based LSIs were also collected and defined on the basis of review of all *International Classification of Diseases, Ninth Revision, Clinical Modification* procedure codes entered into the trauma registry on this cohort of patients. The *International Classification of Diseases, Ninth Revision, Clinical Modification* codes were classified into 13 major categories, with 88 LSI procedures defined. LSIs were then based on a consensus recommendation of a multidisciplinary panel of trauma experts. In addition, Abbreviated Injury Scale values were recorded along with the calculated Injury Severity Score (ISS). Lastly, final diagnosis, intensive care unit admission, and outcome (mortality) were also recorded.

The data collection units consisted of a Propaq 206EL (Welch Allyn, Skaneateles Falls, NY) vital signs monitor with a built-in Acuity RS-232 serial communications port or a PIC 50 (Welch Allyn) defibrillator/vital signs monitor. A rugged iPAQ (Talla-tech RPDA, Tallahassee, FL) Personal Digital Assistant was attached to the Propaq serial port to capture and store the streamed vital signs and waveforms.

Monitor data streams consisted of both waveform data representing the digitized values of the sampled waveform sensor and numeric values consisting of the monitor interpreted values for the attached sensors. PIC50 data sets were stored in the built-in PCMCIA memory card. Data from the Propaq were streamed at a rate of 1 Hz for the numeric vital signs and 182 Hz for the ECG waveforms. PIC50 and Propaq numeric data were obtained every 3 minutes from the event queue generated in the memory card or Personal Digital Assistant. All waveforms on the PIC50 were captured at 375 Hz. Included in the numeric data collection set were the mean, systolic, and diastolic noninvasive blood pressures, the ECG-derived heart rate, SpO_2 -derived heart rate, noninvasive blood pressure-derived heart rate, SpO_2 percent values, EtCO_2 values, and respiratory rate. A single research nurse was used to enter the information generated by the monitors and extracted from the chart review for each patient.

Data were stored and retrieved using the Trauma Vitals database (<http://traumavitals.tamu.edu>) system currently being developed and used by the U.S. Army Institute of Surgical Research, Ft. Sam Houston, Texas. This system provides a data warehousing capability for storing and correlating prehospital patient data from incident pickup until delivery to the hospital. Patient outcome was also included as part of the standard data set for final outcome correlations and analyses. Using a Web-enabled interface, a research nurse at the receiving hospital created a unique incident record composed of the automatically captured data, the emergency run sheet information, hospital procedures and interventions, operative interventions, transfusions, and final patient outcome. Data were then extracted from the system through a series of database queries on the different stored data fields.

Analysis of the data was performed using the SAS system running under Windows XP.²³ The null hypothesis was rejected at $p < 0.05$. All data sets collected from the cohort (demographics/patient information, single point vital signs, and continuous measurements) were grouped by their instrumentation requirements into three nondisjoint groups. A manual group (MG), Group 1, contained all data items that required no instrumentation to obtain. These included the palpable pulse character (radial, femoral, and carotid), capillary refill (normal or delayed), and the motor or verbal components of the Glasgow Coma Scale. The eye component of the GCS was not included in this group because of the need for a light source for diagnosis. Patient demographic information was also included in this group. However, only data that could be available in the field were used for the analysis (i.e., sex, approximate age, race, mechanism of injury). A semiautomated group (SG), Group 2, contained all the variables from the MG group and vital signs that required minimal instrumentation. These variables included the GCS eye component and pulse oximetry values. SpO_2 values used for the analysis were defined as the first viable (nonzero) value recorded by the monitor at the scene. Group 3 (fully automated [AG]) included all variables from the previous MG and

SG groups and all fully automated vitals signs recorded by the prehospital vital signs monitor. These variables included noninvasive blood pressure (systolic, diastolic, and mean), heart rate (pulse), EtCO_2 , and respiration rate.

Univariate analysis was performed on each of the values within the individual groups and measured for their particular predictive power for determining the need for an LSI in the field and/or in the hospital. Univariate analysis only suggests possible differences that may exist between subjects who received an LSI compared with those who did not receive an LSI. This analysis does not account for the redundancies that exist between variables and the interrelationships that may exist between them when group variables are analyzed together. To better understand the relationship between different variables and the need for an LSI, a multivariate analysis was performed using a logistic regression model and measured against the combined predictive power for LSI within the group. This analysis calculated which sets of variables within a specified group best match the need for LSI when examined together. Finally, receiver operating characteristic (ROC) curves were calculated for each of the three groups on the basis of the results of the multivariate analysis. ROC curves were calculated for patients that had prehospital LSIs, hospital LSIs, and the total LSIs (hospital and/or prehospital).

RESULTS

Univariate analysis of the individual vitals signs revealed that most common vital sign measurements used in the field (manual or automated) were predictors for an LSI to some degree (Table 2). However, in this analysis, the radial pulse character was found to have the best predictive power for the need of a prehospital LSI in non-head-injured patients. Demographic data were not found to be predictors for either prehospital or hospital LSIs, including both the age and race of the patient, with the exception of mechanism of injury, which was found to be a predictor of LSI.

When performing a multivariate analysis of all MG variables, the radial pulse along with the verbal and motor components of the GCS were found to have the best predictive power for needing a prehospital LSI with a ROC curve area of 97% (0.969). Similarly, the SG was found to also have an ROC area of 97% (0.97), with the best predictors being the radial pulse and the motor and eye components of the GCS. Figure 1 shows the resulting ROC curves for the three groups for determination of prehospital LSIs.

Examination of the AG group revealed that addition of all automated vitals signs measured by the monitor did not statistically improve the ROC curve values from the previous groups for prediction of a prehospital LSI (Table 3). ROC curve analysis resulted in a value of 97% (0.975) for the predictive value of Group 3. Addition of the periodic automated blood pressure monitoring was not associated with an increase in the ability to predict a prehospital LSI with the patient cohort. For this group, the variables used as predictors in the SG group remain the same for prehospital LSIs.

Table 2 Univariate Analysis for Predictors of Total LSIs

Variable	No. patients (%)	No. LSI (%)	Odds Ratio*	95% CI†	p Value‡
Overall	381 (100.0)	126 (33.1)			
Age (yr)					
18–25	84 (22.0)	31 (36.9)	0.99	0.98–1.01	0.87
26–34	107 (28.1)	34 (31.8)			(0.90)
35–48	94 (24.7)	30 (31.9)			
49–90	96 (25.2)	31 (32.3)			
Male	273 (71.8)	90 (33.0)	0.97	0.60–1.56	0.90
Female	107 (28.2)	36 (33.6)	1.0		
Blunt	341 (90.0)	107 (31.4)	0.46	0.23–0.90	0.02
Penetrating	38 (10.0)	19 (50.0)			
Radial pulse					
Absent	13 (3.4)	13 (100.0)	73.12+	4.30–1242	0.0001
Weak	26 (6.8)	21 (80.8)	11.41	4.18–31.15	0.0001
Normal	342 (89.8)	92 (26.9)	1.0		
GCS Motor					
1	48 (12.6)	48 (100.0)	399.15+	24.24–6571	0.0001
2	2 (0.5)	2 (100.0)	20.58+	1.00–434.5	0.005
3	3 (0.8)	3 (100.0)	28.81+	1.47–565.7	0.0006
4	12 (3.1)	7 (58.3)	5.80	1.78–18.95	0.002
5	28 (7.4)	10 (35.7)	2.30	1.01–5.26	0.04
6	288 (75.6)	56 (19.4)	1.0		
GCS Eye					
1	63 (16.5)	60 (95.2)	85.88	25.89–284.83	0.0001
2	11 (2.9)	4 (36.4)	2.45	0.69–8.70	0.15
3	37 (9.7)	11 (29.7)	1.81	0.84–3.92	0.12
4	270 (70.9)	51 (18.9)	1.0		
GCS Verbal					
1	62 (16.3)	58 (93.6)	62.60	21.50–182.25	0.0001
2	12 (3.2)	7 (58.3)	6.04	1.83–20.00	0.001
3	3 (0.8)	2 (66.7)	8.63	0.77–97.52	0.04
4	86 (22.6)	18 (20.9)	1.14	0.61–2.13	0.67
5	218 (57.2)	41 (18.8)	1.0		
SBP field					
<99 or UR	92 (24.2)	38 (41.3)	0.97	0.96–0.98	0.0001
100–118	95 (24.9)	18 (18.9)			(0.0001)
120–132	96 (25.2)	7 (7.3)			
132–198	98 (25.7)	12 (12.2)			
DBP Field					
<56 or UR	117 (30.7)	40 (34.2)	0.97	0.95–0.98	0.0001
58–70	88 (23.1)	12 (13.6)			(0.0001)
72–82	86 (22.6)	10 (11.6)			
84–125	90 (23.6)	13 (14.4)			
Oxygen saturation					
UR	64 (16.8)	18 (28.1)	0.95	0.93–0.97	0.0001
14–95	80 (21.0)	28 (35.0)			(0.0001)
96–99	91 (23.9)	4 (4.4)			
100	146 (38.3)	25 (17.1)			

*Odds ratio computed using the logit method with a zero-cell correction. For dichotomous variables, the odds ratio represents a test against a reference category whose referent odds ratio is equal to 1. For continuous data, the odds ratio refers to the increase in odds associated with a one-unit increase in the variable value. Although continuous data are presented in quartiles, the odds ratios are against the continuous variable.

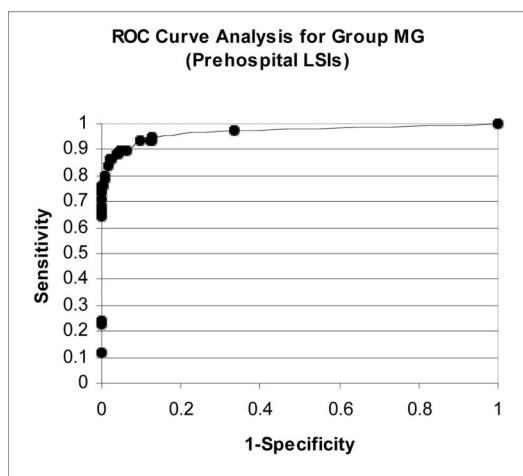
†95% confidence interval. This reflects the units against which its companion odds ratio is computed. Confidence intervals are test-based.

‡p = probability of type I statistical error (common p value). Values without parentheses are Pearson χ^2 probabilities. Probability values in parentheses are univariate logistic regression likelihood ratio p values.

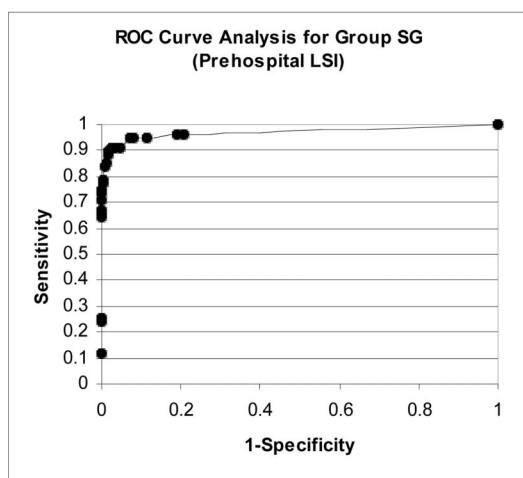
UR, unreadable for patient or technical reasons.

Analysis of the three groups was also performed for predicting the need for a hospital LSI. Results of this analysis show that the overall predictive power of all the groups decreased significantly from the 97% ROC area results of the prehospital LSIs but were still statistically significant at pre-

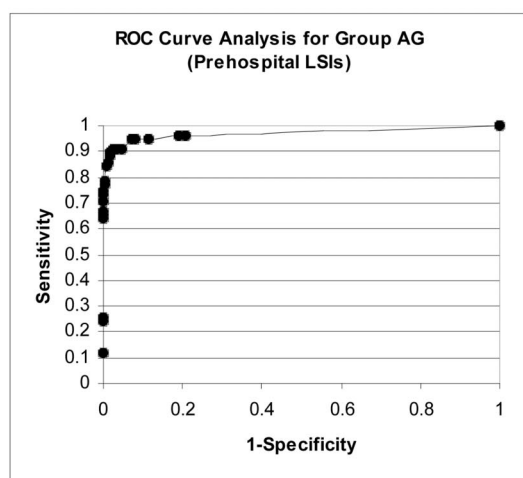
dicting a hospital LSI. Groups MG and SG had an ROC area curve of 62% (0.619 and 0.616, respectively). However, addition of the fully automated monitoring in the AG group added a statistically significant predictor for hospital LSIs in the systolic blood pressure. ROC curve area for the AG group



(a)



(b)



(c)

Fig. 1. ROC analysis curves for prehospital LSIs. (a) MG group, (b) SG and AG groups. ROC curve results for predicting the need for a prehospital LSI of the three groups. (a) ROC curve for the manual group, (b) ROC curve for the semiautomated group, (c) ROC curve for the fully automated group.

Table 3 Results of ROC Curve Analysis for the Three Groups

Model	ROC Area		
	Prehospital LSI	Hospital LSI	Overall LSI
Group 1	96.9	61.9	80.4
Group 2	97.0	61.6*	80.7
Group 3	97.5	71.7*	84.6

*Different $p < 0.05$. No other significant differences.

Group 1 model, radial pulse character, GCS motor, GCS verbal; Group 2 model, radial pulse character, GCS motor, GCS eye; Group 3 model, radial pulse character, GCS motor, GCS eye, systolic blood pressure.

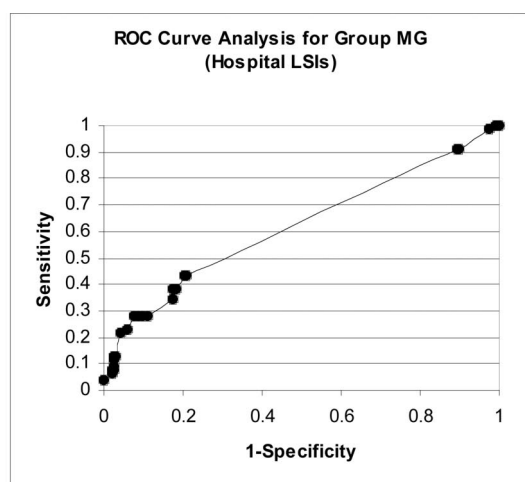
was found to be 72% (0.72), with the predictor variables being the radial pulse, the motor and eye components of the GCS, and the systolic blood pressure. Figure 2 shows the ROC curve results for predicting the need of a hospital LSI. The three curves maintain a significant deviation from the diagonal and remain statistically significant.

When the three groups were analyzed for predictive power for the overall LSIs (prehospital and/or hospital), all groups had significant increases in their respective ROC area from the hospital LSIs. However, the area values for all groups remained below the 97% areas for the prehospital LSI analysis. The MG and SG groups resulted in similar ROC curves, with statistically insignificant differences (80% vs. 81%). ROC area for the AG group increased to 85% (0.846). However, this was found to still be statistically insignificant compared with the MG and SG results. Furthermore, patients with abnormal pulse character (weak or absent) and abnormal GCS motor and verbal component values had a probability of needing an overall LSI of 88%. Figure 3 shows the resulting ROC curves for prediction of overall LSIs. Addition of field SpO₂ values in the SG and AG groups was not found to be predictive of either field or hospital LSIs.

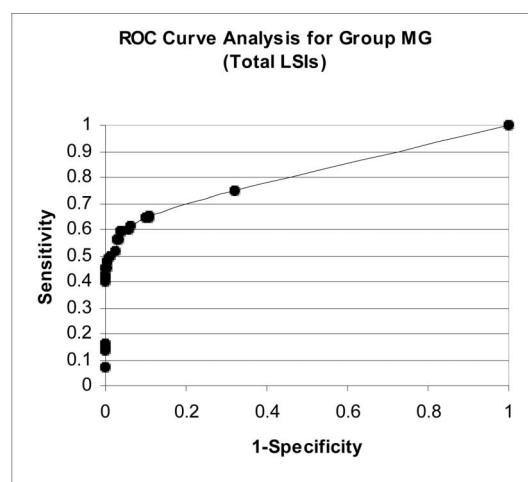
DISCUSSION

Several approaches have been developed for triage and diagnosis based on vital signs and measurements that can be obtained noninvasively in the field through a variety of methods. However, many of these approaches assume the availability of some minimal medical equipment for obtaining the required vital signs necessary for the algorithm. Furthermore, under some circumstances, such as a battlefield or mass casualty event, even common medical instruments (e.g., a sphygmometer) may not be available to assist in the evaluation of the patient.

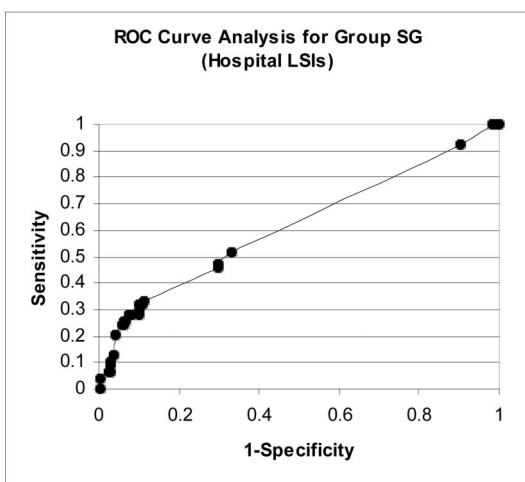
The results of this study suggest that currently available medical monitoring equipment in the prehospital setting that is limited in its capacity to provide medics with trend analysis add little advantage in predicting the need for an LSI in non-head-injured casualties when the GCS score and pulse character can be determined. In fact, this study suggests that the need for an LSI can be predicted on the basis of very



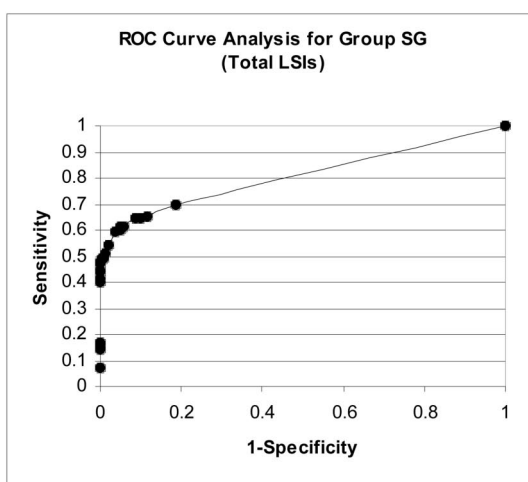
(a)



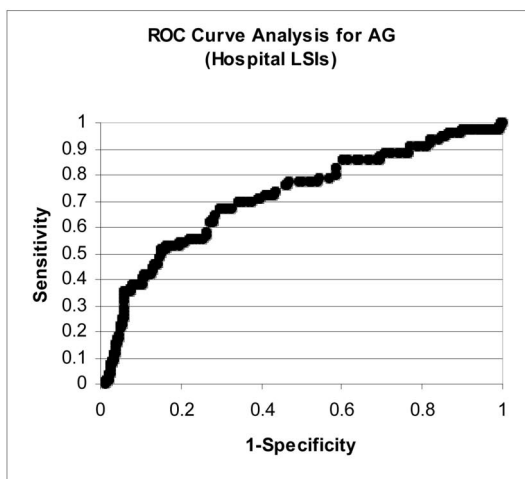
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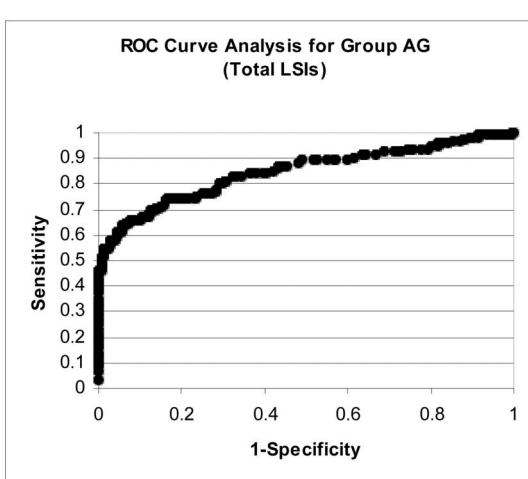
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(b)



(c)



(c)

Fig. 2. ROC analysis curves for hospital LSIs. (a) MG group, (b) SG group, (c) AG group. ROC curve results for predicting the need for a hospital LSI of the three groups. (a) ROC curve for the manual group, (b) ROC curve for the semiautomated group, and (c) ROC curve for the fully automated group.

Fig. 3. ROC analysis curves for total LSIs. (a) MG group, (b) SG group, (c) AG group. ROC curve results for predicting the need for any LSI (prehospital or hospital) of the three groups. (a) ROC curve for the manual group, (b) ROC curve for the semi automated group, and (c) ROC curve for the fully automated group.

minimal physical examination information. When predicting both prehospital and hospital LSIs, manual and semiautomated measurements have a significant predictive capacity that is only slightly lower than that in the fully automated group. The fact that the manual and semiautomated groups have a statistically insignificant difference in their predictive capacity suggests that adding minimal instrumentation may not result in better triage of patients in the field. The only difference between the MG and SG groups is the replacement of the verbal component of the GCS with the eye component. However, the need to have a light source to determine the eye value for the GCS indicates that diagnosis of a patient would be better served by using the verbal component of the GCS without reducing the diagnosis probability of the patient.

Addition of a blood pressure device increased the overall predictive power for the need of a prehospital LSI of the AG group by 4% (85% vs. 81%) over the SG group. The improvement of LSI prediction added by the electronic systolic blood pressure would indicate that the addition of a sphygmometer or an automated blood pressure device during diagnosis may provide better insight into the status of the patient and whether an LSI will be required in the hospital. However, this analysis revealed that only a marginal improvement can be expected in the resulting diagnosis of the patient, with the differences being statistically insignificant compared with the MG and SG groups.

When dealing with multiple simultaneous casualties, these results could be used to develop new, simple, easy-to-remember triage algorithms and sorting procedures based on tactical limitations and operational constraints of current vital sign monitors. With increased numbers of evaluated patients and prospective validation, these new algorithms could effectively predict the patient's current LSI needs. In the civilian arena, the requirement for overtriage of patients results in large numbers of casualties that are transported to higher level facilities (e.g., trauma center) more frequently than they require. This frequently creates undue strain on the resources of the higher level facilities and reduces the quality of care in cases where an inordinate number of nonqualifying patients need to be processed through the facility. The lack of specificity of the patient's injury status in current triage algorithms will also contribute to the overtriage problem. Using the results presented in this work, new and more efficient civilian triage algorithms could be developed that provide a better indicator of the physiologic requirements of the patient and may be used for a more efficient distribution in the appropriate treatment facility. On the basis of the results from these and other ongoing studies, a new triage methodology has been incorporated in the *Prehospital Trauma Life Support* manual for dealing with both civilian and battlefield trauma patients.²⁴

This study combines prospective physiologic data collection with retrospective chart reviews and thus has some limitations. It would be optimal to prospectively collect all the data used for this analysis. In addition, because of equipment limitations (which have since been resolved), many

patients have missing continuous numeric data. Another limitation of this study is the inability to assess the time course of predicting the need for the requirement of a prehospital or hospital LSI. The clinical effectiveness and outcome of LSI is dependent on early diagnosis and application. A major limitation of current vital sign monitors is their collection of physiologic measurements that do not change until the patient is in a critical status (i.e., blood pressure, SpO₂).²⁵ It therefore may not be unexpected that manual examination in our patient population resulted in similar predictive power for LSI than the use of monitors that add little to the early recognition of cardiovascular collapse. Recent work at the U.S. Army Institute of Surgical Research, Ft. Sam Houston, Texas, indicates that laboratory systems with the ability to provide continuous trend analysis (software algorithms) of such responses as heart rate variability or spontaneous baroreflex sequences may allow the health care provider earlier indicators for need of an LSI than either physical examination or static automated vital signs (before cardiovascular collapse).²⁶ Thus, our results should not be misinterpreted to indicate that the use of automated vital sign monitors cannot provide an advantage to diagnosis and triage of trauma patients.

CONCLUSION

In this cohort of patients, the motor and verbal components of the GCS in addition to the radial pulse character have been found to be the best predictors of the need for an LSI if no electronic monitoring is available. These data show that using existing physical examination methods without instruments results in the ability to predict an LSI equally as well as that provided by a sophisticated electronic monitor. Using a physical examination, the ability to predict the need for a field and/or hospital LSI was statistically the same as that found with the addition of more complex electronic instruments that may not be available in the field.

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DISCUSSION

Dr. Saman Arbabi (Ann Arbor, Michigan): The object of this study was to measure the risk of death associated with hypotension in patients with and without Traumatic Brain Injury (TBI). They used the National Trauma Data Bank. They concluded that systemic hypotension does not increase mortality in TBI patients more than it does for non-TBI patients. I think this is a matter of interpretation. I consider the results to demonstrate synergism between hypotension

and TBI regarding mortality. The authors demonstrated that the odds ratio for the hypotension variables did not change when they constructed their statistical model with or without TBI. However, this does not mean that hypotension has the same effect on mortality in both. Rather, it demonstrates that these terms are independent predictors of mortality. Furthermore, a logistic model for blunt trauma without TBI is probably a deficient model with low predictability. The more traditional way is to look at interaction terms between head injury and hypotension. My first question to the authors is whether the authors considered interaction terms between TBI, hypotension, and other variables?

Another way of looking at this is to consider relative or absolute difference in mortality. Before hypotension, the observed mortality rate was 4.4 percent in TBI and 0.5 percent in non-TBI, a difference of 4 percent. After hypotension, the absolute difference in mortality rate increased to 20 percent, from 4 percent to 20 percent. The mortality rate for TBI became 33 percent and for non-TBI it became 13 percent, again, suggesting that hypotension has synergism with TBI, not just additive. My second question is, did you calculate the rate of adjusted expected mortality in your full model when you considered all the terms including TBI and hypotension; and did you compare the expected mortalities?

My third question is regarding introduction of complications in the model to predict mortality. Complications can be considered an outcome that may be predicted from other variables in your model, such as admission blood pressure, GCS and so on. Do you think that introduction of complications in your model is appropriate?

Dr. Ajai K. Malhotra (Richmond, Virginia): Just as you say, the previous studies may have left the impression that the hypotension and TBI is more harmful than hypotension and non-TBI. Similarly, I don't think you should leave the impression that hypotension is equally bad in TBI and non-TBI, because mortality is only half of the story. In TBI, the other half is functional outcome and although you have cited it as a limitation, I think it should be emphasized that in TBI patients, hypotension is much more dangerous maybe than in non-TBI patients.

Dr. Faran Bokhari (Chicago, Illinois): I have a question about the classification of hypotension. I'm wondering if there's a large misclassification error of who is hypotensive and who is not, because if you have just one blood pressure, as you acknowledged, you might be just mixing both the groups, and that's why you're not seeing any differences. So when you look at your mortalities based on ISS scores are they in line with traditionally accepted mortalities in brain injured and non-brain injured patients?

Dr. Shahid Shafi (Dallas, Texas): I'm going to start off with Dr. Arbabi's questions. His first question was about the use of interaction terms, especially between TBI and hypotension and the variables. No, we did not include any interaction terms in our model, but to account for that, we applied the logistic regression model separately to brain injured and

non-brain injured patients, and by stratifying that, it does take into account, to a certain degree, the effect of potential interactions.

I would still argue that there's no synergism between mortality from hypotension and presence of head injuries, because when you look at the slides that I showed you about severity of brain injury, if there was synergism between mortality and severity of brain injury, that synergism should show up when you stratify by brain severity. More severely injured patients should have a higher mortality, which we did not see.

The second question about where you compared the mortality rate between TBI and non-TBI patients, we specifically avoided doing that for two reasons. One, those mortality rates that I showed you are crude mortality rates, which are not adjusted for differences between the groups. That is the bigger issue that the previous studies just looked at crude mortality rates and compared them to show a difference. We don't think that's appropriate, because like I showed earlier, there's a difference in injury severity, there's a difference in patient population, and so those numbers are not directly comparable to each other.

Your second question was about expected mortality rates. We did not calculate expected mortality rate, and I think that's a good suggestion that I will take back to my office.

Your final question was about complications. We felt it was important to include complications in the model, because we did not think we had enough predictors of complications, and complications are, by themselves, independent predictors of survival and so we wanted to take them into account.

Dr. Malhotra, your issue about functional outcome is actually very important to us, as well. We recognize that as a definite shortcoming, because a secondary brain injury may not affect survival. It may only affect functional outcomes, and that would be a good question to answer. We did attempt to look at the National Trauma Data Bank to look for functional outcomes. They do report functional independence measures, but it was reported in only a minority of patients. It's one of the variables which has a large number of missing information.

Dr. Bokhari, we are cognizant of the fact that there may be a misclassification error, but our results to change, the misclassification between hypotensive and normotensive patients in TBI and non-TBI patients will have to be systematically different from each other for the results to change.

We don't have any reason to believe that there will be a systematic difference in that measurement, and our mortality, like I showed in one of the earlier slides, the crude mortality between the two groups was different, and some of it was due to differences in ISS. We do not believe that misclassification error is existent to a fact that it may change our results. We don't believe that.